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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,956	10/08/2003	Matthias Finckh	930008-2113	6079

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FROMMER LAWRENCE & HAUG
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NEW YORK, NY 10151

EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/680,956	FINCKH ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/08/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS and preliminary amendment, both filed 10/08/2003.

Claims 1-12 are pending and included in the prosecution.

Specification

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required under the title "Abstract" or "Abstract of the Disclosure".

3. The use of the trademarks "Durotak 2287" and "Durotak 2516" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4, and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 contains the trademarks/trade names "Durotak 2287" and "Durotak 2516". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe acrylate based polymers and, accordingly, the identification/description is indefinite.

Regarding claims 9-12, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claims are rendered indefinite by raising a question or doubt introduced by the limitations following the expression "preferably" or "especially" because it is subject of more than one interpretation, and one interpretation would render the claim unpatentable over the prior art. In the present instance, claim 9 recites the broad limitation of oxybutynin amount of "5-40%" and the narrower limitation

"10-35%", and even more narrower limitation "15-30%". Claim 10 recites the broad limitation of aloe vera extract amount of "10-25%" and the narrower limitation "12-20%", and even more narrower limitation "14-18%". Claim 11 recites the broad limitation of the amount of cross-linking agent of "0.1-5.0%" and the narrower limitation "0.3-3.0%", and even more narrower limitation "0.5-2.0%". Claim 12 recites the broad limitation of the surface area of the delivery system of "5-80 cm^2" and the narrower limitation "10-60 cm^2", and even more narrower limitation "20-50 cm^2".

Additionally, claims 9-12 recite bracketed limitations, and it is not certain if these limitations are part of the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of WO 93/23025 ('025) in view of JP 61-129117 ('117) and US 6,198,017 ('017).

WO '025 teaches transdermal patch to deliver oxybutynin comprising backing layer, matrix comprising the oxybutynin in an adhesive polymer and permeation enhancer, and a release liner (abstract; page 7, lines 17-30; figure 1). The size of the patch ranges from 5-50 cm^2 (page 13, lines 21-23).

WO '025 does not teach the aloe vera in the composition or the cross-linking agent as claimed by claims 1 and 5. The reference does not teach the acrylic adhesive as claimed in claim 4, the vegetable oil used to extract the aloe vera and its amount as claimed in claims 6 and 7, or the amount of different ingredients as claimed in claims 9-11.

JP '117 teaches cataplasm composition containing aloe vera extract in an amount of equal or more than 5 wt% of the whole composition to provide high permeability of the main drug component to the skin and meanwhile provides improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after the use of the cataplasm (see the provided abstract).

US '017 teaches medical pressure sensitive adhesive comprising acrylic adhesive cross-linked with 2.5% of aluminum acetylacetonate providing excellent

adherence to wet and dry skin and can be removed from the skin without residue (abstract; col.2, lines 3-12; col.3, lines 16-18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal device to deliver oxybutynin comprising polymer adhesive matrix comprising the drug and permeation enhancer as disclosed by WO '025, and replace the permeation enhancer with aloe vera extract disclosed by JP '117, motivated by the teaching of JP '117 that aloe vera extract provides high permeability of the main drug component to the skin and meanwhile provides improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after use, with reasonable expectation of having transdermal device to deliver oxybutynin comprising polymer adhesive matrix comprising oxybutynin and aloe vera extract that provides high permeability of oxybutynin to the skin, improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after use of the polymer adhesive matrix.

Additionally, one having ordinary skill in the art at the time of the invention would have used acrylic adhesive cross-linked with aluminum acetylacetonate as a polymer matrix as disclosed by US '017, motivated by the teaching of US '017 that acrylate adhesive cross-linked with aluminum acetylacetonate provides excellent adherence to wet and dry skin and can be removed from the skin without residue, with reasonable expectation of having transdermal device to deliver oxybutynin comprising cross-linked acrylic adhesive matrix that has been cross-linked with aluminum acetylacetonate that

provides excellent adherence to wet and dry skin and can be removed from the skin without residue providing comfortability and pleasance to the user.

The combination of the references does not teach the amount of the drug as instantly claimed by claim 9, the vegetable oil used to extract the aloe vera and its amount as claimed in claims 6 and 7.

The claimed amount does not impart patentability to the claims, absent evidence to the contrary.

The oil-based aloe vera extract is step directed to method of extraction of the aloe vera and the method of extraction of the aloe vera does not impart patentability to the product claims. The source of aloe vera does not impart patentability to the claims, absent evidence to the contrary.

10. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 5,602,839 ('839) in view of JP 61-129117 ('117) and US 6,198,017 ('017).

US '839 teaches transdermal patch to deliver oxybutynin comprising backing layer, matrix comprising the 20% oxybutynin in cross-linked acrylic adhesive polymer and 10-20% permeation enhancer, and a release liner (abstract; col.4, lines 1-5; col.6, lines 59-60;col.7, lines 5, 28, 51; col.9, lines 60-67).

US '839 does not teach the aloe vera in the composition as claimed by claim 1 or the specific cross-linking agent as claimed by claim 5. The reference does not teach the vegetable oil used to extract the aloe vera and its amount as claimed in claims 6 and 7,

the amount the cross-linking agent as claimed in claim 11, or the size of the patch as claimed in claim 12.

JP '117 teaches cataplasm composition containing aloe vera extract in an amount of equal or more than 5 wt% of the whole composition to provide high permeability of the main drug component to the skin and meanwhile provides improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after the use of the cataplasm (see the provided abstract).

US '017 teaches medical pressure sensitive adhesive comprising acrylic adhesive cross-linked with 2.5% of aluminum acetylacetonate providing excellent adherence to wet and dry skin and can be removed from the skin without residue (abstract; col.2, lines 3-12; col.3, lines 16-18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal device to deliver oxybutynin comprising cross-linked acrylic adhesive matrix comprising the drug and permeation enhancer as disclosed by US '839, and replace the permeation enhancer with aloe vera extract disclosed by JP '117, motivated by the teaching of JP '117 that aloe vera extract provides high permeability of the main drug component to the skin and meanwhile provides improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after use, with reasonable expectation of having transdermal device to deliver oxybutynin comprising cross-linked acrylic adhesive matrix comprising oxybutynin and aloe vera extract that provides high permeability of oxybutynin to the skin, improved viscoelastic properties, stability, and preferable

adhesiveness to the skin leaving no residual on the skin after use of the polymer adhesive matrix.

Additionally, one having ordinary skill in the art at the time of the invention would have used acrylic adhesive cross-linked with aluminum acetylacetonate as an adhesive polymer for the matrix as disclosed by US '017, motivated by the teaching of US '017 that acrylate adhesive cross-linked with aluminum acetylacetonate provides excellent adherence to wet and dry skin and can be removed from the skin without residue, with reasonable expectation of having transdermal device to deliver oxybutynin comprising cross-linked acrylic adhesive matrix that has been cross-linked with aluminum acetylacetonate that provides excellent adherence to wet and dry skin and can be removed from the skin without residue providing comfortability and pleasance to the user.

The combination of the references does not teach the vegetable oil used to extract the aloe vera and its amount as claimed in claims 6 and 7, or the size of the patch as claimed in claim 12.

The oil-based aloe vera extract is step directed to method of extraction of the aloe vera and the method of extraction of the aloe vera does not impart patentability to the product claims. The source of aloe vera does not impart patentability to the claims, absent evidence to the contrary.

The size of the patch does not impart patentability to the claims, absent evidence to the contrary.

Minor Informalities

11. Claims 1-12 objected to because of the following informalities: the plant species should be *italized*. Appropriate correction is required.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,356,811 teaches that aloe vera preparation that can effectively employed as a vehicle for active agents because of its the ability to penetrate the skin surface and carry other medication with it is especially useful (col.7, lines 58-61; col.8, lines 1-3). US 6,455,066 teaches topical formulation in the form of patch or monolithic patch comprising local anesthetic in a pressure sensitive adhesive, and aloe vera extract as permeation enhancer (abstract; col.3, lines 10-14; col.5, line 52; col.8, lines 7-10). The patch is inert, non-allergenic, non-toxic, and compatible with the drugs and has rapid onset of action (col.2, lines 61-64). Aloe vera is provided in soy oil base (col.4, lines 55-57).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

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